

**REMARKS**

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance. The Examiner is thanked for considering claims 7 and 15 to be allowable if rewritten in independent form.

**I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Claims 1, 2, 4 and 6-18 are pending. Claims 1, 2, 14 and 17 are amended, without prejudice. Applicants expressly state that the claims, as amended, are intended to include and encompass the full scope of any equivalents as if the claims had been originally filed and not amended. Thus, Applicants hereby expressly rebut any presumption that Applicants have narrowed or surrendered any equivalents under the doctrine of equivalents by amending the claims, or by presenting any remarks in this paper, and in no way do Applicants disclaim any of the territory between the original claims and the amended claims with respect to any equivalent subject matter.

The amendments are fully supported by the specification and the original claims. Therefore, no new matter is added.

As this paper is submitted within the three-month term for reply set by the September 13, 2004 Office Action, no fee is believed to be due. If, however, any fee is deemed necessary for consideration of this paper, authorization is hereby given to charge the amount of any such fee, or credit any overpayment, to Deposit Account No. 08-2525.

**II. 35 U.S.C. §112, SECOND PARAGRAPH, REJECTION**

Claims 2, 14, 17 and 18 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The amendments to the claims render the rejection moot.

Consequently, reconsideration and withdrawal of the Section 112, second paragraph, rejection are respectfully requested.

**III. 35 U.S.C. §102 REJECTION**

Claims 1, 2, 4, 6, 8-14 and 16 were rejected under 35 U.S.C. §102 as allegedly being anticipated by JP 11230910 to Hirotooshi as well as by the compounds listed on document C11. Although Applicants disagree with the Examiner's reasoning, the amendments to the claims obviate the rejection.

Consequently, reconsideration and withdrawal of the Section 102 rejection are respectfully requested.

**CONCLUSION**

In view of the remarks and amendments herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The Examiner is invited to contact the undersigned to discuss any issues with respect to this application.

Respectfully submitted,

  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,991	03/15/2004	Luca Claudio Gobbi	21021 US1	1721

151 7590 09/13/2004  
HOFFMANN-LA ROCHE INC.  
PATENT LAW DEPARTMENT  
340 KINGSLAND STREET  
NUTLEY, NJ 07110

EXAMINER

AULAKH, CHARANJIT

ART UNIT PAPER NUMBER

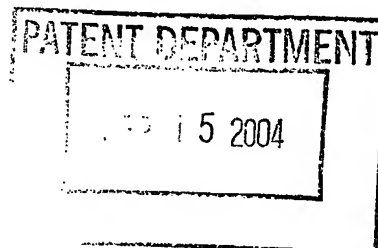
1625

DATE MAILED: 09/13/2004

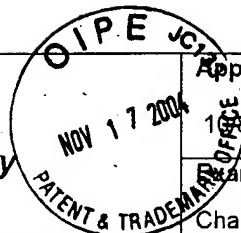
Please find below and/or attached an Office communication concerning this application or proceeding.

RESPONSE DUE: <u>March 13, 2005</u>
STATUTORY PERIOD EXPIRES: <u>March 13, 2005</u>

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## Office Action Summary



Application No.

10/300,991

Examiner

Charanjit S. Aulakh

Applicant(s)

GOBBI ET AL.

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4 and 6-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6, 8-14 and 16-18 is/are rejected.
- 7) ☒ Claim(s) 7 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 10/321,692.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

### DETAILED ACTION

1. According to a preliminary amendment filed on March 15, 2004, the applicants have canceled claims 3 and 5 and furthermore, have amended claims 1, 4, 8, 9, 11, 13, 15 and 17.
2. Claims 1, 2, 4 and 6-18 are now pending in the application.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 17 and 18, the term ---prophylaxis---is indefinite since it is not clear how the instant compounds having inhibitory activity against DPP-IV will be able to prevent diabetes or non-insulin dependent diabetes mellitus where GLP-1 ( stimulator of insulin release ) is not involved in the etiology of diabetes. The applicants are suggested to delete this term. Also, the applicants are suggested to include the term ---therapeutically effective amount of --- before --- a compound ---in last line.

5. Claim 2 recites the limitation "aryl and substituted aryl for variable R1" in claim 1.

There is insufficient antecedent basis for this limitation in the claim.

6. Claim 14 recites the limitation "Phenyl for variable R1 ( see last compound )" in claim

1. There is insufficient antecedent basis for this limitation in the claim.

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***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4, 6, 8-14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirotoishi ( JP 11230910, cited on applicants form 1449 ) as well as by compounds listed in citation no. C11, cited on applicants form 1449 ).

The benzo[a]quinolizin-2-amine compounds ( RN 39630-39-2, RN 39630-42-7, RN 109964-42-3 and RN 96614-27-6 ) anticipate the instant claims when R1 represents methyl, ethyl or isobutyl group and both R2 and R3 represent methoxy groups in the instant compounds of formula (I).

***Allowable Subject Matter***

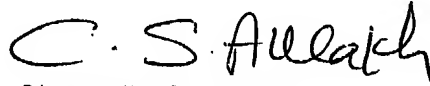
8. Claims 7 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charanjit S. Aulakh  
Primary Examiner  
Art Unit 1625

FFICE

④

## 21021 US1

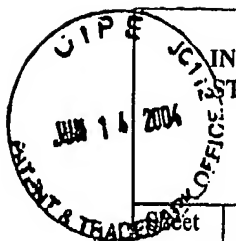
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## FOREIGN PATENT DOCUMENTS

Examiner Signature		Date Considered	
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<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation or abstract is attached.





(Use several sheets if necessary)

Application Number	10/800,991
Filing Date	March 15, 2004
First Name Inventor	Luca Claudio Gobbi
Group Art Unit	
Examiner Name	
Attorney Docket Number	21021 US1

[illegible]

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language Translation or abstract is attached.

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